Claims 60-92 remain pending.

Applicants' specie election is acknowledged.

Applicants arguments filed 10/11/07 have been considered and found persuasive. The previously imposed rejections are withdrawn. Claims 63-65, 67-92 are now rejoined with the elected claims. Claims 60-92 are examined in this Office action.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-68 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The cited claims are drawn to a method of treating cancer, i.e., any form of cancer. The term at issue would encompass at least the following:

> breast cancer, prostate cancer, lung cancer, colon cancer, rectal cancer, bladder cancer, Non-Hodgkin Lymphoma, melanomas of the skin, cancer of the Kidney and Renal Pelvis, pancreatic cancer, oral cancer, esophagal cancer, ovarian cancer, thyroid cancer, stomach cancer, brain cancer, multiple myeloma, liver and intrahepatic bile duct cancer, acute myeloid leukemia, chronic lymphocytic leukemia, Hodgkin's Lymphoma, testicular cancer, intestinal cancer, chronic myeloid leukemia, acute lymphocytic leukemia,

> cancer of the vulva, gallbladder cancer, malignant mesothelioma, bone cancer, joint cancer, cancer of the hypopharynx, cancer of the eye, cancer of the nose, cancer of the ureter, cancer of the peritoneum, gastrointestinal carcinoid tumors, bladder cancer, melanoma, breast cancer, non-hodgkin's lymphoma, ovarian cancer, endometrial cancer, pancreatic cancer, kidney cancer (renal cell), prostate cancer, leukemia, non-melanoma cancer of the skin. Also included are sarcomas and carcinomas, such as the following: fibrosarcoma, myxosarcoma, liposarcoma, chondrosarcoma, osteogenic sarcoma, chordoma, angiosarcoma, endotheliosarcoma, lymphangiosarcoma, lymphangioendotheliosarcoma, synovioma, mesothelioma, ewing's tumor, leiomyosarcoma, rhabdomyosarcoma, colon carcinoma, pancreatic cancer, ovarian cancer, prostate cancer, squamous cell carcinoma, basal cell carcinoma, adenocarcinoma, sweat gland carcinoma, sebaceous gland carcinoma, papillary carcinoma, papillary adenocarcinoma, cystadenocarcinoma, medullary carcinoma, bronchogenic carcinoma, renal cell carcinoma, hepatoma, bile duct carcinoma, choriocarcinoma, seminoma, embryonal carcinoma, Wilms' tumor, cervical cancer, testicular tumor, lung carcinoma, small cell lung carcinoma, bladder carcinoma, epithelial carcinoma, glioma, astrocytoma, medulloblastoma, craniopharyngioma, ependymoma, pinealoma, hemangioblastoma, acoustic neuroma, oligodendroglioma, meningioma, melanoma, neuroblastoma, retinoblastoma, leukemia, lymphoma, multiple myeloma, Waldenströom's macroglobulinemia, and heavy chain disease.

It is noted that Garanger (*Molecular Therapy* **12**(6) 1168-1175, 2005) discloses that the compound designated RAFT(cRGD)$_4$ exhibited some efficacy in the treatment of mice implanted with melanoma xenografts. This compound doesn't actually fall within the scope of claim 60, since claim 60 requires a therapeutic moiety on one face and a recognition molecule on the other, whereas the compound RAFT(cRGD)$_4$ bears only recognition moieties on one face. But even assuming, for purposes of discussion, that RAFT(cRGD)$_4$ did fall within the scope of claim 60, at best the claims would be enabled for treatment of melanoma. There is no evidence, or reason to believe, that the claimed compounds will be effective against any and all forms of cancer.

The following references discuss the matter of various attempts by oncologists to treat cancer: Viallet (*Lung Cancer* **15** (3) 367-73, 1996); Kemeny (*Seminars in Oncology* **21**

(4 Suppl 7) 67-75, 1994); Newton (*Expert Opinion on Investigational Drugs* **9** (12) 2815-29, 2000); Giese (*Journal of Cancer Research and Clinical Oncology* **127** (4) 217-25, 2001); Garattini (*European Journal of Cancer* **37** Suppl 8 S128-47, 2001); Ragnhammar (*Acta Oncologica* **40** (2-3) 282-308, 2001). Even if it should turn out, at some point in the future, that claims 67 and 68 are enabled for treatment of melanoma, There is no basis for extrapolating to any of the other various forms of cancer.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to practice the invention of claims 67-68.

- Claim 62 is objected to. In the last line of the claim, the phrase "precursor thereof" is used. This should be preceded by the indefinite article, i.e., **a** precursor thereof.

- Claim 63 is objected to. It appears that the term "epitpic" is misspelled.

Claims 61, 62, 64-92 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 61 recites the following:

  The ... cyclopeptide… wherein at least one recognition molecule is a ligand… … and on the other of its faces…".

  This latter phrase ("on the other of its faces") implies that the first ligand is on the opposite face; however, the first part of the claim permits the ligand to be on either face. Thus, the question arises, is the apotogenic peptide on the same face as the ligand, or the opposite face? The same issue applies in the case of claim 62.

- Claim 62 makes reference to a "molecule of the … radioemitter type". This renders the claim indefinite as to the manner in which, or the extent to which the detectable molecule must resemble a radioemitter in order to qualify as a "molecule of the radioemitter type". Similarly, claim 65 makes reference to a "carbohydrate type".

- In claim 64, the phrase "recognition molecules" (in the plural) lacks antecedent basis, notwithstanding the presence of the term "recognition molecule" (in the singular) in claim 60.

- Claim 65 is drawn to a peptide, not a composition. At the same time however, the claim suggests the presence of an "immunoadjuvant". However, this term refers to something that is used in a mixture, generally an additive which enhances immune response. Thus, there is a contradiction. Is claim 65 drawn to a single, pure compound, or is the claim drawn to a mixture?

- Claim 66 is drawn to a composition. A composition, however, requires at least two components. If the composition contains only a single pure compound, then it is not a composition. Thus, claim 66 is mandating the presence of some other compound or material, yet provides no clues as to what it might be. Is it a carrier? Is it a peptide? Is in an inactive agent?

- Claim 68 is indefinite as to the host. Is it a test tube? Is it a frog?

- In claim 69, lines 9-10, the phrase "the cyclopeptide framework" lacks antecedent basis.

- Claim 69 is missing a process step. The last two lines of the claim mandate that a "molecule of interest" is grafted onto the peptide via an oxime bond. Yet the claim makes no mention of any oxime precursor. Thus one of the questions that arises is, does the oxime bond form spontaneously, or does a chemist have to synthesize it? Then there is the question of whether the "molecule of interest" is the same as, or different from the molecule of therapeutic interest, or the molecule of diagnostic interest.

- In claim 79, the terms "the oxyamine function" and "the aldehyde function" both lack antecedent basis.

- Claim 81 recites the following:

  "the amine and hydroxyl functions …. oxidation of which releases an aldehyde group".

  Certainly, if one oxidizes the hydroxyl group of serine (and is able to stop the oxidation at the aldehyde stage), one can obtain an aldehyde group. But the issue in claim 81 is more complicated. Claim 81 requires, at a minimum, that one oxidize a protected hydroxyl group. It is not clear how applicants propose to do this. More puzzling is how applicants propose to convert the amino group of serine to an aldehyde group, even setting aside the question of whether the amino group is protected or not.

- In claim 87, the phrase "molecules of interest" is recited. Note that "molecules" is in the plural, rather than the singular. One has to go back to claim 60 to find any mention of a "molecule of interest", and as it happens, the term "molecule" is used in the singular in that claim. Given the mismatch between the plural and the singular, one can say that the phrase "molecules of interest" (in claim 87) lacks antecedent basis.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654